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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/659,980 | 09/10/2003 | Timothy A. Hovanec | P 0284781 081289 | 6075 |

7590 02/17/2006

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EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1656

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/659,980 | HOVANEK, TIMOTHY A. | |
| | Examiner | Art Unit | |
| | David J. Steadman | 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Application

- [1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
- [2] Claims 1-32 are pending in the application.
- [3] Receipt of a substitute sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, and a statement that the paper copy of the substitute sequence listing introduces no new matter, all filed on 1/23/2004, is acknowledged.
- [4] In order to perfect sequence compliance, applicant is required to submit an amendment directing entry of the substitute sequence listing filed on 1/23/2004 into the specification.
- [5] Receipt of information disclosure statements, filed on 6/8/2004, 10/22/2003, and 9/10/2003, is acknowledged.
- [6] The priority claim at the first paragraph of the specification should be updated to provide the status of non-provisional application 09/573,684.

Election/Restrictions

- [7] Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-7 and 15-21, drawn to a method for detecting and determining the quantity of bacteria that oxidize ammonia to nitrite using a probe

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comprising SEQ ID NO:5 and variants thereof, classified in class 435, subclass 6.

- II. Claims 1-7 and 15-21, drawn to a method for detecting and determining the quantity of bacteria that oxidize ammonia to nitrite using a probe comprising SEQ ID NO:8 and variants, classified in class 435, subclass 6.
- III. Claims 8-14 and 22-28, drawn to a method for detecting and determining the quantity of bacteria that oxidize ammonia to nitrite using a probe comprising SEQ ID NO:21, classified in class 435, subclass 6.
- IV. Claims 29-30, drawn to a DNA chip comprising a probe comprising SEQ ID NO:5, classified in class 422, subclass 68.1.
- V. Claims 29-30, drawn to a DNA chip comprising a probe comprising SEQ ID NO:8, classified in class 422, subclass 68.1.
- VI. Claims 31-32, drawn to a DNA chip comprising a probe comprising SEQ ID NO:21, classified in class 422, subclass 68.1.

[8] The inventions are distinct, each from the other because:

[9] The methods of Groups I-III are independent as they comprise different active method steps, utilize different products, and/or yield different results.

[10] The DNA chips of Groups IV-VI each comprises a DNA with a distinct nucleotide sequence as evidenced by their different sequence identifiers. Also, no single DNA chip of Groups IV-VI would render the others obvious to one of ordinary skill in the art.

[11] The DNA chip of Group IV is unrelated to the methods of Groups II-III as it is neither made nor used by the methods of Groups II-III.

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[12] The DNA chip of Group V is unrelated to the methods of Groups I and III as it is neither made nor used by the methods of Groups I and III.

[13] The DNA chip of Group VI is unrelated to the methods of Groups I-II as it is neither made nor used by the methods of Groups I-II.

[14] The DNA chip of Group IV and the methods of Groups II-III, the DNA chip of Group V and the methods of Groups I and III, and the DNA chip of Group VI and the methods of Groups I-II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods can be practiced using a different product, e.g. a protein chip. See particularly claims 7, 14, 21, and 28.

[15] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, the inventions of Groups I-VI are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. In view of the recited limitations of the claims of each invention, a patent and non-patent literature search and optionally sequence search for each Group is required. As such, co-

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examination of the inventions of Groups I-VI would require a serious burden on the examiner.

[16] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[17] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

[18] Claims 1, 15, and 29 will be examined only to the extent the claims read on the elected subject matter.

Notice of Possible Rejoinder

[19] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

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whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 6:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656